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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/086,940

03/01/2002

Sean T. O'Mara

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SEED INTELLECTUAL PROPERTY LAW GROUP LLC  
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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/28/2006

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/086,940	Applicant(s) O'MARA, SEAN T.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 66-71 and 73-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66-71 and 73-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

1. This Office action is in response to the amendment and 37 CFR 1.131 affidavit filed on September 27, 2006.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 66,67,71,73,74,78 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti ('614).

As to claim 66, Bonutti (col.4, lines 62-66; col.22, line 44-col.23, line 41) discloses a method comprising: inserting an intubation-tube placement device (50,50b), secured to an intubation tube (38), into a patient's oral cavity; detecting the cartilaginous rings of

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the trachea via at least one tactile-accentuator device (52) coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords (col.4, lines 62-66); and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords (col.8, lines 48-67). The step of "...detecting the cartilaginous rings of the trachea...", is inherent in the process of using the intubation tube placement device of Bonutti. The text of Bonutti (col.4, lines 62-66) discloses the leading end portion (52) of the intubation-tube placement device to be formed of resiliently compressible material, readily deflected by engagement with the vocal cords or folds and by engagement with the surface of the trachea. The resiliently deformable, readily deflected leading end portion (52) of Bonutti is expressly disclosed as being in contact with the tracheal surface; therefore, any additional obstacle that is encountered during the intubation process including cartilaginous rings of the trachea would also cause deflection of the leading end portion and thereby "detect" any such obstacle including cartilaginous rings.

As to claim 67, Bonutti discloses said intubation-tube placement device comprises a light source (400).

As to claim 71, Bonutti discloses said forcing the intubation-tube placement device through the patient's vocal cords comprises: applying axial pressure along the intubation-tube placement device such that the intubation-tube placement device moves into the patient's trachea (col.5, lines 42-55).

As to claim 73, Bonutti discloses a method comprising: inserting an intubation-tube placement device (50,50b) having an exploratory portion (52) shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion, into a patient's oral cavity, detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device (52) coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords (col.4, lines 62-66); and axially sliding an intubation tube (38) along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords (col.8, lines 48-67). The step of "...detecting the cartilaginous rings of the trachea...", is inherent in the process of using the intubation tube placement device of Bonutti. The text of Bonutti (col.4, lines 62-66) discloses the leading end portion (52) of the intubation-tube placement device to be formed of resiliently compressible material, readily deflected by engagement with the vocal cords or folds and by engagement with the surface of the trachea. The resiliently deformable, readily deflected leading end portion (52) of Bonutti is expressly disclosed as being in contact with the tracheal surface; therefore, any additional obstacle that is encountered during the intubation process including cartilaginous rings of the trachea would also cause deflection of the leading end portion and thereby "detect" any such obstacle including cartilaginous rings.

As to claim 74, Bonutti discloses said intubation-tube placement device comprises a light source (400).

As to claim 78, Bonutti discloses said forcing the intubation-tube placement device through the patient's vocal cords comprises: applying axial pressure along the intubation-tube placement device such that the intubation-tube placement device moves into the patient's trachea (col.5, lines 42-55).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 68-70,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti ('614) in view of Flam ('386).

The difference between Bonutti and claim 68 is suctioning materials from a vicinity of the patient's vocal cords via a suction tube formed by the intubation-tube placement device.

Flam, in a method of inserting an intubation-tube placement device, teaches suctioning materials from a vicinity of the patient's vocal cords via a suction tube formed by the intubation-tube placement device (col.7, lines 50-59) for the purpose of clearing mucous and debris from a patient's respiratory tract. Flam also discloses the use of the suction tube for insufflating a patient for providing breathable gas to a patient during the intubation process.

It would have been obvious to modify the intubation-tube placement device of Bonutti to provide a suction tube for suctioning materials from a vicinity of a patient's vocal cords because it would have provided a means for clearing mucous and debris from a patient's respiratory tract as well as provided a means for delivering breathable gas to a patient during the intubation process as taught by Flam.

As to claim 69, Bonutti as modified by Flam teaches the intubation-tube placement device forming a hollow tube (suction lumen extends entire length of device as disclosed at col.7, lines 50-59 of Flam).

As to claim 70, Flam teaches the suction tube formed by the intubation tube placement device comprises: the intubation-tube placement device forming a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); an anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion; a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device, and the trailing portion coupled to said intubation-tube placement device such that the channel substantially aligns with hollow tube.

Claims 75-77 are substantially equivalent in scope to claims 68-70 and are included in Bonutti as modified by Flam for the reasons set forth above with respect to claims 68-70.

### ***Response to Arguments***

6. The affidavit filed on September 27, 2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the Bonutti ('614) reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Bonutti ('614) reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

On the first page of the "Department of the Army-United States of America: Invention Disclosure" in the section entitled "Information and Dates Concerning this Invention," Applicant is required to answer the following two questions: 1) "On what date did you first think of this invention?" and 2) "What records show this?". In response to the first question, Applicant has provided the required information, which has since been deleted as permissible under United States Patent and Trademark Office practice. However, to the second question, Applicant has recorded the word "None". Examiner believes the use of the word "None" effectively serves as an admission by the Applicant of insufficient proof of Applicant's effective filing date of invention and insufficient showing of diligence on Applicant's part. Because of this, the Examiner has found this affidavit to be insufficient, as the information having been submitted does not effectively overcome the prior art of record.




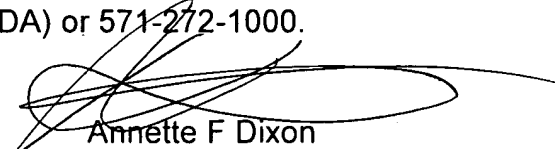
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
TEENA MITCHELL  
PRIMARY EXAMINER

  
Annette F Dixon  
Examiner  
Art Unit 3771  
December 19, 2006